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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/568,544

09/22/2006

Reiji Kannagi

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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,544	<b>Applicant(s)</b> KANNAGI ET AL.	
	<b>Examiner</b> MEERA NATARAJAN	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/17/2006, 09/22/2006, 06/17/2008</u> .                      | 6) <input type="checkbox"/> Other: _____                          |



## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I, Claims 1-6 in the reply filed on 03/18/2008 is acknowledged.
2. Claims 7-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/18/2008.
3. Claims 1-6 will be examined on the merits.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. The Claim recites "cells expressing HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase and that is absent or almost absent in cells expressing GlcNAc6ST-1 or GlcNAc6ST gene". It is unclear what is meant by "that is absent or almost absent". Is Applicant referring to the antigen, HEC-GlcNAc6ST gene, reactivity of the antibody, or

GlcNAc-6-sulfotransferase being absent? It is also unclear what is meant by "almost" absent. The metes and bounds of the term "almost" are unclear. Clarification is required.

8. Claims 1, 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The Claims recite the term "react", "reacting" or "reactivity". These terms refer to a chemical reaction whereas it is well known in the art that antibodies "bind" to an antigen and do not "react with an antigen". Does the applicant intend for the antibody to be catalytic? Clarification is required.

10. also antibodies don't "react" with antigens unless they are catalytic. They bind to antigens. Do they mean a catalytic antibody?

11. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. The claim recites "MECA-79 antibody or its equivalent". It is unclear what is meant by "equivalent". Does applicant mean equivalent in structure, function, affinity, etc.? Clarification is required.

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Streeter et al. (JCB, Vol. 107, pp.1853-1862, Nov. 1988) as evidence by Hemmerich et al. (Immunity, Vol 15, pp.237-247, August 2001).

15. The claims are drawn to a method for examining colorectal cancer and colorectal adenoma comprising assaying the reactivity of an antibody to tissues, body fluid or feces of patients, or extracts thereof, wherein said antibody is MECA-79 (commercially available from BD Pharmingen) and reacts with an antigen that is present in cells expressing HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase.

16. Streeter et al. teach a method of staining tissue from the small intestine and colon with the MECA-79 antibody (see Figures 1-3). Binding of MECA-79 to its antigen which is present in cells expressing HEC-GlcNAc6ST gene encoding GlcNAc-6-sulfotransferase would be an inherent feature of the antibody and any method in which the antibody was used to stain tissue sections/samples would inherent perform the method claimed. Hemmerich et al. further support this inherency by disclosing staining of tissue samples expressing HEC-GlcNAc6ST by the MECA-79 antibody (see Figure 5).

**Conclusion**

17. Claims 1-6 are rejected.
18. No claim is allowed.
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

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... [1]

/Larry R. Helms/  
Supervisory Patent Examiner, Art Unit 1643